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The original study protocol of this trial, approved by the Ethical Committee of Reggio Emilia (Italy) is in Italian language.

A translated English version of the original protocol is shown below.

Introduction

Since the introduction of the International Classification of Functioning, Disability and Health (ICF) in 2001, the World Health Organization has been promoting the implementation of a client-centered, biopsychosocial approach in healthcare programs and rehabilitation services [1]. This conceptual framework focuses on individual functioning more than on disease and contemplates the health condition as a dynamic status resulting from a comprehensive view of biological, individual and social perspectives [1].

The ICF approach is particularly appropriate for patients during rehabilitation, as the latter relies on the interaction between functions, activities, participation and contextual factors [2,3]. Indeed, regardless of the underlying pathology, patients undergoing rehabilitation habitually manifest similar basic needs, while their level of functioning and advanced needs, namely those related to leisure, productivity, and social role, may be different [4]. This was brought to light also by Phipps S. et al.'s work [5], which showed that when rehabilitation focuses on individual significant activities, gains in performance and satisfaction are noticeable both in patients with traumatic brain injury and in those with stroke. Similarly, occupational therapy (OT) has proven to be beneficial in patients with different types of cancer when based on patient requests [6].

In line with this approach, an assessment tool based on the complexity of patients' care needs has been validated to classify individuals who require rehabilitation interventions [7-8]. This

classification makes it possible to create homogeneous populations according to the complexity of their care needs, not to their diagnosis. Moreover, this approach may facilitate conducting valid rehabilitative studies, whose results may be highly generalizable.

A complex patient suffers from a disease that affects clinical stability and functional autonomy. This patient is dependent on others when carrying out daily activities and manifests regular need for medical monitoring, for specialized nursing care and for two or more specialized interventions, e.g., occupational therapy, physiotherapy, or speech therapy. Frequently, complex patients need special aids to carry out tasks. Thus, complex patients benefit from multiprofessional rehabilitation, which may include client-centered OT interventions.

Our research group recently conducted an observational study aimed at identifying the needs of complex inpatients in a rehabilitation ward to develop a client-centered OT intervention targeted at this population [9]. To our knowledge, no well-designed randomized clinical trial on the efficacy of OT in the rehabilitation process of complex patients has yet been published.

We thus decided to conduct this ICF concept-based pilot randomized controlled trial (RCT) in order to detect the effect size of an experimental, client-centered OT intervention in a population of complex patients in their rehabilitation phase.

Materials and Methods

This single-center, open-label RCT with two parallel groups was designed in accordance with the CONSORT statement and the Helsinki declaration. The study was approved by the local Ethics Committee (19/03/2014, n.325).

Study objectives

The primary aim of this exploratory study was to estimate the effects of experimental OT on complex patients' perception of occupational performance during relevant activities. If the experimental OT proved beneficial, its effect size estimate would be used to plan a powered randomized controlled trial.

The secondary aim was to verify the feasibility of the OT experimental intervention in a mixed hospital-home-based setting for a population of complex patients undergoing rehabilitation.

Further objectives were to estimate the effects of experimental OT on: a) complex patients' self-perception of occupational satisfaction with the way they perform their relevant occupational activities; b) mood disturbances; c) independence in basic and instrumental activity of daily living (ADL); d) reintegration to normal social activities and quality of life (QoL).

Participants

All adult patients admitted to the Physical and Rehabilitation Medicine ward (PRM) of the Local Health Authority - Research Institute (AUSL-IRCCS) of Reggio Emilia, Italy and deemed complex on the basis of the Rehabilitation Complexity Scale-Extended (RCS-E) were screened for eligibility. The RCS-E score ranges from zero to 22, with the cut-off value for complexity set at nine [7].

Exclusion criteria were the presence of severe cognitive impairment, verified by the physiatrist through direct observation and exploratory interview (evaluating memory, orientation in time and space, adequacy to the context, absence of disinhibition or frontal disorders, risk evaluation), primary psychiatric disorders, communication disability and language barriers that, in the opinion of the healthcare team, would prevent the patient from participating in the experimental OT program. Furthermore, to allow assessment of the

feasibility of the experimental intervention, patients living over 30 km from the hospital and patients for whom it was known a priori that they would be discharged to a retirement home were excluded.

We also excluded complex patients already recruited in a competing clinical trial (ISRCTN75290225).

Informed consent was obtained from all participants by physicians during the admission process.

Outcomes

The primary outcome measure for this study was the performance score of the Canadian Occupational Performance Measure (COPM) [10]. The COPM is a standardized client-centered measure designed to detect changes in occupational performance and satisfaction over time, based on patient perception. The COPM is administered by a semi-structured interview resulting in a list of up to five priority occupational activities, suited to satisfy relevant needs in three areas: self-care, productivity, and leisure.

The feasibility of the experimental OT intervention was assessed by calculating the ratio between the number of patients who completed it according to the predefined posology and the total number of patients enrolled in the intervention group (IG). We established a priori that the study would be judged feasible if 75% of patients randomized to the intervention group completed the experimental OT. Given the complex nature of these patients, we also collected information on the appropriateness of estimates made a priori regarding the timing of achievement of treatment goals and the level of independence achieved by any participant enrolled in the IG.

Further outcome measures applied to verify the effects of experimental OT in complex patients were the satisfaction score of the COPM [10], the Hospital Anxiety and Depression

Scale (HADS) [11], the modified Barthel Index (MBI) [12], the Instrumental Activity Daily Living scale (IADL) [13], the Reintegration to Normal Living Index (RNLI) [14] and the Short-Form 12 (SF-12) [15].

Assessments

Study participants were assessed at baseline (T0), upon discharge (T1), and at follow up (T2) (Table1).

Table 1: Clinical outcome measures and study assessments.

	T0 Baseline (within one week from admission to PRM ward)		T1 Discharge (within 3 days up to discharge)	T2 Follow up (45 ± 15 days from discharge)
Comorbidities (CCI)	X	Randomization		
Performance in carrying out occupational activities (COPM)	X		X	X
Satisfaction in carrying out occupational activities (COPM)	X		X	X
Mood disturbances (HADS)	X		X	X
B-ADL (MBI)	X		X	X
I-ADL (IADL)	X		X	X
Reintegration to Normal Living Index (RNLI)			X	X
Quality of life (SF-12)			X	X

Legend: PMR= Physical Medicine and Rehabilitation; COPM= Canadian Occupational Performance Measure; CCI= Charlson Comorbidity Index; HADS= Hospital Anxiety and Depression Scale; B-ADL= Basic-Activities of Daily Living; MBI= Modified Barthel Index; I-ADL= Instrumental – Activities of Daily Living; IADL= Instrumental Activities of Daily Living; RNLI= Reintegration to Normal Living Index; SF-12= Short Form-12.

Baseline assessment (T0) was carried out within 1 week from admission to the PRM ward and before randomization. At T0 the degree of comorbidity was assessed using the Charlson Comorbidity Index (CCI), which is also a measure of burden of disease [16]. T0 also

included the assessments of occupational performance and satisfaction, mood disturbances, B-ADL, and I-ADL.

T1 took place within three days before discharge from the PRM ward. Except for comorbidities assessment, it included all the above-mentioned measurements plus the RNLI and QoL assessments.

The follow up (T2) took place at the patient's domicile 45 ± 15 days from discharge and included all the assessments administered at T1.

T2 assessments and all the COPM interviews were collected by the occupational therapists. Given the aim of this study, the rehabilitation team was integrated with two occupational therapists working specifically on this trial. T0 and T1 assessments were collected by members of the rehabilitation health care team (physiatrists, physiotherapists, occupational therapists, and nurses), as per habit of the ward.

Data regarding the feasibility of the experimental OT intervention in this specific hospital-home-based setting were collected by researchers throughout the trial and were unified at T2.

Randomization

Shortly after T0, patients were randomly assigned to the control group (CG) or to the IG, with a 1:1 allocation ratio. The Research and Statistics unit of the AUSL – IRCCS generated the computerized random allocation lists and proceeded with the concealed allocation of patients to groups, once the patients had been enrolled by clinicians and after T0 assessment. Patients assigned to CG were provided with the standard care already in place in the PRM ward. Patients assigned to IG followed the experimental OT intervention delivered in addition to standard care.

Control group

The CG underwent standard care, which consisted of task-oriented rehabilitation targeted at the recovery of autonomy in B-ADL (basic activity of daily life). Patients were cared for by

an interdisciplinary multiprofessional rehabilitation team composed of physiatrists, nurses, physiotherapists, and speech therapists, as well as by a psychologist and social worker when necessary.

During the post-acute phase, standard care was carried out daily, six days a week, during hospitalization. Standard care also included some (one to three) therapeutic authorizations to go home for the weekend in the pre-discharge phase. On the basis of pre-discharge assessment, rehabilitation was continued post-discharge on an outpatient basis when deemed necessary by the rehabilitation team.

Intervention group

The experimental OT intervention was provided by the occupational therapists in addition to standard care and was based on the Canadian Model of Occupational Performance and Engagement [17]. Experimental OT aimed at satisfying the occupational needs in the areas of self-care, productivity, and leisure that emerged through the COPM assessment at baseline. During the post-acute phase, experimental OT was delivered daily, five days a week, during hospitalization. In this setting, experimental OT was targeted at the accomplishment of occupational needs in the self-care area and, when needed, in the productivity and leisure areas.

After discharge from the PRM ward, experimental OT was delivered at the patient's domicile for up to ten sessions over a period of one to two months. In this setting, experimental OT was targeted at the accomplishment of occupational needs related to productivity and leisure areas and to any residual goals of the self-care area.

The experimental OT intervention was planned by the occupational therapists, was tailored to each patient, and was carried out according to the following phases:

- 1) Identification of three to five subjective priority occupational needs, which become the focus of the experimental OT intervention;

2) Observation of patient while performing the activities related to the occupational needs in the hospital or at home after discharge;

3) Setting the treatment goals (accomplishment of occupational activity) for each occupational need;

Plus, for each goal set:

5) Definition of the implementation time;

6) Definition of the level of independence expected at the end of the treatment;

7) Planning the appropriate OT intervention (i.e., content and modalities) according to a specific planning checklist (Table 2);

Table 2. Planning checklist of OT intervention for each goal set.

Phase	Activity	Options	
A	Definition of the OT rehabilitative approach	restorative	compensative
B	Definition of treatment posology	number of sessions	
		frequency of sessions	
		duration of each session	
C	Definition of any supports and/or facilitation strategies to be used during sessions (e.g., aids, caregivers, facilities, etc.)		
D	Definition of the intervention setting/s		
E	Group sessions	yes	no

Withdrawal from trial

Participants were withdrawn from the study for any of the following reasons:

- a) Serious adverse events or death
- b) Patient referred to other wards for clinical reasons
- c) Patient discharged to a nursing home after in-hospital rehabilitation
- d) Patient lost to follow up
- e) Patient withdrawal of consent to participate

All withdrawals with specific reason were recorded. Data collected up to the patient's discontinuation of the study were analyzed with the intention-to-treat approach.

Data analysis

The analyses were carried out by the Research and Statistics units of the AUSL – IRCCS of Reggio Emilia. This was an exploratory study as there was no information to set the sample size based on statistical criteria. Thus, it was considered appropriate to randomly recruit 40 subjects to estimate the average effect size of experimental OT measured by the performance score of the COPM. To compute the effect size, we compared the changes in COPM performance score between IG and CG in the T2-T0 time frame. Furthermore, to evaluate the clinical relevance of this finding, we matched it with the minimal clinically important difference of the COPM performance score, which was estimated equal to two points [18]. In addition, to estimate the effects of experimental OT in this population the mean variations of the all the outcome measures were compared between groups at T1-T0, T2-T1 and T2-T0 time frames.

Descriptive statistics were performed to investigate the sample characteristics; mean and standard deviation were chosen to summarize continuous variables, while absolute and relative frequencies (n, %) were used for categorical variables.

The assumption of normality for continuous variables was verified statistically using the Shapiro-Wilk test.

To test differences between the groups, numerical data were compared using the Student's t-test and Mann-Whitney U test, and categorical data were compared using the Pearson's chi-squared test or the Fisher's exact test. The threshold for statistical significance was set at $p < 0.05$. IBM SPSS Statistics 23 for Windows (SPSS, Chicago, IL) was used for statistical analyses.

References

- [1] World Health Organization. International classification of functioning, disability and health: ICF. Geneva: WHO; 2001.
- [2] Stucki G, Ewert T, Cieza A. Value and application of the ICF in rehabilitation medicine. *Disabil Rehabil.* 2002 Nov 20;24(17):932-8.
- [3] Wade D. Rehabilitation - a new approach. Part two: the underlying theories. *Clin Rehabil.* 2015 Dec;29(12):1145-54.
- [4] Müller M, Grill E, Stier-Jarmer M, Strobl R, Gutenbrunner C, Fialka-Moser V, Stucki G. Validation of the comprehensive ICF core sets for patients receiving rehabilitation interventions in the acute care setting. *Journal of rehabilitation medicine.* 2011 Jan 5;43(2):92-101.
- [5] Phipps S, Richardson P. Occupational therapy outcomes for clients with traumatic brain injury and stroke using the Canadian Occupational Performance Measure. *American Journal of Occupational Therapy.* 2007 61(3): 328-334.
- [6] College of Occupational Therapists. Occupational therapy intervention in cancer: Guidance for professionals, managers and decision-makers. London: COT; 2004.
- [7] Turner-Stokes L, Scott H, Williams H, Siegert R. The Rehabilitation Complexity Scale—extended version: detection of patients with highly complex needs. *Disabil Rehabil.* 2012;34(9):715-720.
- [8] Rodà F, Agosti M, Corradini E, Lombardi F, Maini M, Brianti R. Cross-Cultural adaptation and preliminary test-retest reliability of the Italian version of the Complexity Rehabilitation Scale-Extended (13th Version). *Eur J Phys Rehabil Med.* 2014;51(4):439-446.

- [9] Schiavi M, Costi S, Pellegrini M, Formisano D, Borghi S, Fugazzaro S. Occupational therapy for complex inpatients with stroke: identification of occupational needs in post-acute rehabilitation setting. *Disability and Rehabilitation*. 2017; 1-7.
- [10] Law M, Baptiste S, Carswell A, McColl MA, Polatajko H, & Pollock N. Canadian Occupational Performance Measure (COPM). CAOT Publications ACE. 2014.
- [11] Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatr Scand*. 1983;67(6):361-370.
- [12] Shah S, Cooper B, Maas F. The Barthel Index and ADL evaluation in stroke rehabilitation in Australia, Japan, the UK and the USA. *Aust Occup Ther J*. 1992;39(1):5-13.
- [13] Lawton MP, Brody EM. Assessment of older people: self-maintaining and instrumental activities of daily living. *Gerontologist*. 1969;9(3):179-186.
- [14] Wood-Dauphinee SL, Opzoomer MA, Williams JI, Marchand B, Spitzer WO. Assessment of global function: The Reintegration to Normal Living Index. *Arch Phys Med Rehabil*. 1988;69:583-590.
- [15] Apolone G, Mosconi P, Quattrocioni L, Gianicolo EAL, Groth N, Ware JE. Questionario sullo stato di salute Sf-12, Versione Italiana 2005. Ed. Guerini e Associati.
- [16] Charlson M, Szatrowski TP, Peterson J, Gold J. Validation of a combined comorbidity index. *Journal of clinical epidemiology*. 1994;47(11):1245-1251.
- [17] Polatajko HJ, Townsend EA, Craik J. Canadian model of occupational performance and engagement (CMOP-E). In *Enabling occupation II: Advancing an occupational therapy vision of health, well-being & justice through occupation*. E.A. Townsend & H.J. Polatajko, Eds. Ottawa, ON: CAOT Publications ACE. 2007;23:22-36.
- [18] Law M, Baptiste S, Carswell-Opzoomer A, McColl MA, Polatajko H, & Pollock N. Canadian Occupational Performance Measure. Toronto: CAOT Publications ACE. 1991.